

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

03 Jun 2026

### Long-term effect of topical Dorzolamide and Latanoprost on Refraction in patients with primary open-angle glaucoma

#### Protocol summary

##### Summary

In this clinical trial, two groups of patients with primary open angle glaucoma (intraocular pressure [IOP] between 21 and 30 mm Hg) are included. Each group contains 44 patients who are older than 16 years. Exclusion criteria include the use of topical and systemic carbonic anhydrase inhibitors and IOP > 30 mm Hg. One group will randomly receive 2% dorzolamide eye drops three times a day and the other group will randomly receive 0.005% latanoprost eye drops once a day. Examinations include manifest refraction using an auto-refractometer (average of three readings), best-spectacle corrected visual acuity with full-correcting glasses using Snellen chart, IOP measurements using Goldmann Applanation tonometer, slit lamp biomicroscopy of cornea and anterior chamber, non-dilated funduscopy, and automated perimetry (Humphrey perimetry). Central corneal thickness (CCT), anterior chamber depth (ACD), and lens thickness (LT) will be measured using IOLMaster. The measurements by IOLMaster as well as refraction will be repeated after the instillation of cyclopentolate eye drops. Two weeks after the initiation of anti-glaucoma medications, all above mentioned examinations will be repeated at least 2 hours after the use of drops. To evaluate the long-term effects, these measurements will be performed 6±1 weeks afterwards. The participants will have an access to the examiner whenever they have blurred vision. A statistical analysis will be used to compare the study groups in terms of any significant differences in refraction, CCT, ACD, and LT as well as to find any correlation between the use of each medication and blurred vision.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2013052813505N1**

Registration date: **2014-09-07, 1393/06/16**

Registration timing: **registered\_while\_recruiting**

Last update:

Update count: **0**

##### Registration date

2014-09-07, 1393/06/16

##### Registrant information

###### Name

Hossein Mohammad-Rabie

###### Name of organization / entity

Shahid Beheshti University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

00982173430- 00982177558081

###### Email address

h\_mohammadrabie@sbm.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Shahid Beheshti University of Medical Sciences

##### Expected recruitment start date

2013-06-21, 1392/03/31

##### Expected recruitment end date

2015-10-23, 1394/08/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Long-term effect of topical Dorzolamide and Latanoprost on Refraction in patients with primary open-angle glaucoma

## Public title

Effect of topical Dorzolamide and Latanoprost on Refraction

## Purpose

Health service research

## Inclusion/Exclusion criteria

Inclusion criteria: all patients with open angle glaucoma; older than 16; with eye pressure of 21 to 30 mm Hg which have not taken any treatment. Exclusion criteria: previous use of systemic or topical dorzolamide; using contact lens since 1 month ago; taking sulfa drug since 1 month ago; lactation; pregnancy (pregnancy reduce eye pressure and increase cornea thickness); cataract; any kind of eye surgery; CD/disc more than 0.8; best visually by less than 20/40 (with using Pin Hole); any neuropathy, any severe damage to visual field; and also any increase in eye pressure more than 30 mm Hg during the study.

## Age

From **16 years** old to **149 years** old

## Gender

Both

## Phase

2-3

## Groups that have been masked

*No information*

## Sample size

Target sample size: **88**

## Randomization (investigator's opinion)

Randomized

## Randomization description

## Blinding (investigator's opinion)

Double blinded

## Blinding description

## Placebo

Not used

## Assignment

Parallel

## Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Shahid Beheshti University of Medical Sciences

##### Street address

Yaman alley, Velenjak av., Chamran subway

##### City

Tehran

##### Postal code

1985717443

#### Approval date

2013-05-19, 1392/02/29

#### Ethics committee reference number

sbmu.rec.1392.61

## Health conditions studied

### 1

#### Description of health condition studied

glaucoma

#### ICD-10 code

H40.1

#### ICD-10 code description

Primary open-angle glaucoma

## Primary outcomes

### 1

#### Description

Refraction

#### Timepoint

2 and 6±1weeks

#### Method of measurement

Autorefractometr

## Secondary outcomes

### 1

#### Description

Visual acuity, thickness of lens and cornea and depth of anterior chamber

#### Timepoint

2 and 6±1weeks

#### Method of measurement

Visual acuity with Snellen chart, thickness of lens and cornea and depth of anterior chamber by IOL Master

## Intervention groups

### 1

#### Description

Control: Including patients who will receive 0.005% latanoprost eye drops once a day for 6±1 weeks.

#### Category

Treatment - Drugs

### 2

#### Description

Control: including patients who will receive 2% dorzolamide eye drops three times a day for 6±1 weeks

#### Category

Treatment - Drugs

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Basir Eye Center

##### Full name of responsible person

DR Mohammad-Rabie

**Street address**

Jamalzadeh Shomalli ave.

**City**

Tehran

## Sponsors / Funding sources

### 1

**Sponsor**

**Name of organization / entity**

Shahid Beheshti University of Medical Sciences

**Full name of responsible person**

DR Mohammad-Rabie

**Street address**

Yaman alley. Velenjak ave. Chamran subway

**City**

Tehran

**Grant name**

**Grant code / Reference number**

**Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Shahid Beheshti University of Medical Sciences

**Proportion provided by this source**

100

**Public or private sector**

*empty*

**Domestic or foreign origin**

*empty*

**Category of foreign source of funding**

*empty*

**Country of origin**

**Type of organization providing the funding**

*empty*

## Person responsible for general inquiries

**Contact**

**Name of organization / entity**

Shahid Beheshti University of Medical Sciences

**Full name of responsible person**

Narges Moslehi Moghaddam

**Position**

MSc of Optometry

**Other areas of specialty/work**

**Street address**

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## Person responsible for scientific

## inquiries

**Contact**

**Name of organization / entity**

Shahid Beheshti University of Medical Sciences

**Full name of responsible person**

DR Mohammad-Rabie

**Position**

Associated professor of ophtalmology

**Other areas of specialty/work**

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## Person responsible for updating data

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Shahid Beheshti University of Medical Sciences

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**Position**

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**Other areas of specialty/work**

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## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**

*empty*

**Study Protocol**

*empty*

**Statistical Analysis Plan**

*empty*

**Informed Consent Form**

*empty*

**Clinical Study Report**

*empty*

**Analytic Code**

*empty*

**Data Dictionary**

*empty*